IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION	MDL No. 2804
This document relates to: *Cleveland Bakers and Teamsters Health and Welfare Fund v. Purdue Pharma L.P.*, No. 18-op-45432	Case No. 17-md-2804 Hon. Dan Aaron Polster

MEMORANDUM IN SUPPORT OF THE MANUFACTURER DEFENDANTS' JOINT MOTION TO DISMISS THE AMENDED COMPLAINT

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Citation	**Docket No.**	**Full title**
1AC	Dkt. 635	Amended Complaint, *Cleveland Bakers and Teamsters Health and Welfare Fund v. Purdue Pharma L.P.*, No. 18-op-45432 (June 18, 2018)
CMO One	Dkt. 232	Case Management Order One, *In re Nat'l Prescription Opiate Litig.* (April 11, 2018)
Summit 2AC	Dkt. 514	Corrected Second Amended Complaint and Jury Demand, *County of Summit, Ohio v. Purdue Pharma L.P.*, No. 18-op-45090 (May 29, 2018)
Summit MTD	Dkt. 499-1	Memorandum of Law in Support of the Manufacturer Defendants' Joint Motion to Dismiss Plaintiffs' Second Amended Complaint, *County of Summit, Ohio v. Purdue Pharma L.P.*, No. 18-op-45090 (May 25, 2018)
Summit Distribs.' MTD	Dkt. 491-1	Memorandum in Support of Distributors' Motion to Dismiss Second Amended Complaint, *County of Summit, Ohio v. Purdue Pharma L.P.*, No. 18-op-45090 (May 25, 2018)
Summit Reply	Dkt. 746	Reply in Support of the Manufacturer Defendants' Joint Motion to Dismiss Plaintiffs' Second Amended Complaint, *County of Summit, Ohio v. Purdue Pharma L.P.*, No. 18-op-45090 (July 13, 2018)
West Boca Compl.	Dkt. 385	Complaint, *West Boca Med. Ctr., Inc. v. AmerisourceBergen Drug Corp.*, No. 18-op-45530 (May 7, 2018)
West Boca MTD	Dkt. 691-1	Memorandum of Law in Support of the Manufacturer Defendants' Joint Motion to Dismiss Plaintiff's Complaint, *West Boca Med. Ctr., Inc. v. AmerisourceBergen Drug Corp.*, No. 18-op-45530 (June 29, 2018)

INTRODUCTION

Plaintiffs, a pair of Ohio-based union health and welfare funds, seek to hold a handful of pharmaceutical manufacturers liable for costs the funds claim to have incurred as a result of the nation's opioid crisis. Like the *Summit* and *West Boca* plaintiffs, these plaintiffs primarily assert claims for the downstream harm that results *after* individuals have become addicted to opioids, such as treatment for addiction, overdose, or similar medical ills. Those claims against the manufacturer defendants,[1] however, fail for the same reasons set forth in the *Summit* and *West Boca* motions to dismiss, including that such harms are too remote and indirect to provide a viable basis for suit. In fact the Sixth Circuit has already held that these sorts of medical costs are too remote and indirect to permit recovery against manufacturers. *Perry v. Am. Tobacco Co.*, 324 F.3d 845, 849 (6th Cir. 2003). That ruling is dispositive of these claims.

Perhaps recognizing this fatal flaw, plaintiffs attempt to plead around it by adding an injury they hope appears more direct: the actual costs of prescription opioids for which the funds either paid or reimbursed their plan enrollees. But this add-on does not save plaintiffs' case.

For one thing, the posited causal chain is fatally attenuated and implausible. Under plaintiffs' legal theory, (a) physicians chose to prescribe opioid medications to plaintiffs' enrollees because of the manufacturer defendants' supposed misrepresentations, rather than the physicians'

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[1] This motion incorporates the definition of "manufacturer defendants" set forth in *Summit* MTD at 1 n.2, plus Par Pharmaceutical, Inc.; Par Pharmaceutical Companies, Inc.; and SpecGx LLC. Defendant Noramco, Inc., a company referenced in the amended complaint as a former affiliate of Johnson & Johnson, *see* 1AC ¶52, joins this motion to the extent applicable. Noramco does not (and did not at all material times relevant hereto) manufacture, package, brand, market, distribute, or sell the finished drug products at issue in this litigation, and it reserves all rights and defenses specific to it. Also, although the arguments raised here apply equally to Teva Pharmaceutical Industries Ltd., Allergan plc, and Mallinckrodt plc, these parties do *not* join this motion for the reasons stated in *Summit* MTD at 1 n.2.

independent medical judgment; (b) those supposed misrepresentations caused pharmacy benefit managers—expert organizations comprising physicians and pharmacists who consider FDA approvals and clinical studies—to recommend including prescription opioids in formularies; (c) based on those recommendations, sophisticated third-party administrators (which manage plaintiffs' prescription drug programs) decided to include various opioids in the approved formulary options they offered to plaintiffs; and (d) as a result, plaintiffs selected one of those options and reimbursed their enrollees for opioid prescriptions, even ones that were (allegedly) medically inappropriate. This lengthy causal chain is stretched far too thin to support liability.

Beyond that, plaintiffs' own actions (and inactions) break the causal chain. As providers of health and welfare benefits, plaintiffs have *chosen* to reimburse their enrollees' opioid prescriptions for long-term treatment of chronic non-cancer pain. They could have chosen to reimburse opioid medications (if at all) only for short-term treatment, or only for cancer pain, or only for acute pain. They did not. Plaintiffs do not even allege that they changed their coverage or formularies after learning of the manufacturer defendants' supposed wrongful conduct.

Compounding these legal flaws is that plaintiffs have not pleaded a cognizable injury. Plaintiffs do not allege facts showing that, for example, they reimbursed opioid medications that were not actually prescribed or that were medically unnecessary or ineffective. They do not allege facts showing that without the supposedly wrongful marketing, they would have categorically disallowed coverage of opioid medications for long-term treatment of chronic non-cancer pain (a dubious proposition, given that FDA has approved many opioid medications for precisely that indication). And they do not allege facts showing that they were unable to recoup their expenditures on prescription opioids through insurance premiums. In other words, the plaintiff health and welfare funds got *exactly* what they paid for—and thus have suffered no cognizable

injury, much less one caused by the manufacturer defendants. Not surprisingly, courts across the country have dismissed nearly identical claims brought by third-party payors seeking to recover the costs of prescription medications under similar circumstances. *See*, *e.g.*, *infra* §I & n.3. For these and other reasons set forth below, the amended complaint should be dismissed with prejudice against the manufacturer defendants.

LEGAL STANDARD

Plaintiffs' claims must meet the plausibility standard of *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and, because they sound in fraud, the particularity standard of Rule 9(b). *See Summit* MTD at 5-6. The amended complaint satisfies neither.[2]

ARGUMENT

I. Plaintiffs have not suffered any cognizable injuries caused by the manufacturer defendants.

As in *Summit* and *West Boca*, plaintiffs' alleged injuries are reimbursements for opioid prescriptions and treatment of individuals' opioid addiction and abuse. *Compare*, *e.g.*, 1AC ¶¶928, 960, 974, 998 *with*, *e.g.*, *Summit* 2AC ¶¶902, 934, 948, 972 and *West Boca* Compl. ¶¶52-58. And as in *Summit* and *West Boca*, plaintiffs' alleged injuries are purely derivative of the affected individuals' injuries and are therefore not cognizable as a matter of law. *See West Boca* MTD §I; *see also Summit* MTD §II.A.1; *Summit* Reply § IV.A.1. In fact the Sixth Circuit, joining "eight other federal circuit[s]," squarely rejected nearly identical claims by third-party payors seeking "to recover the increased costs of health-related expenses due to smoking" from cigarette

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[2] In accordance with CMO One §2(g), the manufacturer defendants raise only certain key "issues common to all manufacturers" that warrant dismissal. The manufacturer defendants expressly reserve the right to later raise additional grounds for dismissal, including defendant-specific challenges (such as insufficient service of process—some manufacturer defendants have not yet been served—or lack of personal jurisdiction). *See* CMO One §2(j).

manufacturers. *Perry v. Am. Tobacco Co.*, 324 F.3d 845, 849 (6th Cir. 2003) (collecting cases). "[T]he plaintiffs' claims [we]re inherently contingent on injury to third-party smokers" and were thus too "indirect" to allow recovery. *Ibid.* Just so here.

Indeed the claims here are even more remote than the plaintiff hospital's claims in *West Boca*. While the hospital is obligated to provide emergency services under federal and state law, plaintiffs here have *voluntarily* chosen to reimburse prescription opioids for long-term treatment of chronic non-cancer pain. Third-party payors who "continue to cover the allegedly falsely advertised drug on their formularies and reimburse members for prescriptions cannot, as a matter of law, establish that they were injured by reason of or were victims of the false advertising." *Teamsters Local 237 Welfare Fund v. AstraZeneca Pharm. LP*, 136 A.3d 688, 696 (Del. 2016) (quotation marks omitted). Nor do plaintiffs' conclusory allegations that they were the targets of the manufacturer defendants' alleged misrepresentations, *see* 1AC ¶¶682-770, save their claims. For one thing, the amended complaint concedes that committees of sophisticated "pharmacists, physicians and practicing participating providers" stood between the manufacturer defendants' alleged marketing activities and plaintiffs' ultimate decision to give prescription opioids "preferred" formulary status. 1AC ¶¶683-685. For another, plaintiffs notably do *not* allege that they would have disallowed coverage of prescription opioids for long-term treatment of chronic non-cancer pain but for the alleged marketing activities. Hardly surprising; after all, FDA has *approved* prescription opioids for this indication, and it is implausible that plaintiffs would have denied coverage to their enrollees for such use. Both factors break the causal chain between the manufacturer defendants' alleged acts and plaintiffs' alleged injuries.

The Seventh Circuit's decision in *Sidney Hillman Health Center v. Abbott Laboratories* is instructive. 873 F.3d 574 (7th Cir. 2017). Two health plans sued a prescription drug manufacturer

for promoting off-label uses for which the drug was allegedly ineffective or harmful. *Id.* at 575. Affirming dismissal of the claims, *Sidney Hillman* concluded that the *patients* who took the drug were the "initially injured parties" and thus the appropriate plaintiffs, not the health plans. *Id.* at 576. And the plans' alleged injuries were wholly speculative because some patients might have benefited from the drug, and some physicians might have prescribed it (or refused to prescribe it) regardless of the manufacturer's promotional campaign. *See id.* at 577. "Disentangling the effects of the improper promotions from the many other influences on physicians' prescribing practices would be difficult," if not impossible. *Ibid.* Accordingly, the health plans had no cognizable injury caused by the manufacturer's promotional scheme—a conclusion *Sidney Hillman* viewed as "so straightforward that" other circuits considering similar claims "have issued nonprecedential decisions" to that effect. *Id.* at 578 (citing cases).

Sidney Hillman's rationale supports dismissal of plaintiffs' claims. In fact it applies with even greater force here, because most of the allegations involve promotions for *on-label* use—that is, for FDA-approved indications. This makes it all the more difficult to "disentangle" the manufacturer defendants' marketing activities "from the many other influences on physicians' prescribing practices." *Id.* at 577. Nor have plaintiffs identified even one prescription opioid they reimbursed that was medically unnecessary or ineffective. Plaintiffs thus got exactly what they paid for and have suffered no injury as a matter of law. *See Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315, 320 (5th Cir. 2002) (plaintiff who "paid for an effective pain killer, and … received just that" got "the benefit of her bargain" and could not allege any injury); *Travelers Indem. Co. v. Cephalon, Inc.*, 32 F. Supp. 3d 538, 555-556 (E.D. Pa. 2014), *aff'd*, 620 Fed. Appx. 82 (3d Cir. 2015) (similar).

To the extent plaintiffs allege that they reimbursed more opioid prescriptions than they

otherwise would have absent the manufacturer defendants' marketing activities, they have not alleged any resulting monetary injury. Generally speaking, "a rational insurer" "charge[s] its enrollees higher premiums" if it offers greater coverage; "[t]hese higher premiums, in turn, would compensate the insurer for its increased number of prescription payments, including payments for prescriptions that were medically unnecessary or inappropriate." *Ironworkers Local Union 68 v. AstraZeneca Pharm., LP*, 634 F.3d 1352, 1360 (11th Cir. 2011). By providing prescription drug coverage to its enrollees, plaintiffs "consciously exposed themselves to pay for all prescriptions of [opioids], including those that were medically unnecessary or inappropriate—even if such prescriptions were birthed by fraud." *Ibid.* As in *Ironworkers*, plaintiffs here "have not ple[aded] any facts to suggest plausibly that they did not charge their enrollees premiums or, in turn, adjust those premiums to compensate for this known risk." *Id.* at 1364. Absent such facts, plaintiffs have not plausibly alleged that they suffered any injury as a result of an increased volume of reimbursable opioid prescriptions.

In short, courts across the country, including the Sixth Circuit, have rejected similar claims by third-party payors seeking to recover the costs of providing covered health-care services to their enrollees. *See Perry*, 324 F.3d at 849 (collecting cases); *Sidney Hillman*, 873 F.3d at 578 (same).[3]

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[3] *See also*, *e.g.*, *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 246-248 (3d Cir. 2012); *Ironworkers Local Union 68 v. AstraZeneca Pharm., LP*, 634 F.3d 1352, 1345-1369 (11th Cir. 2011); *United Food & Commercial Workers Cent. Pa. & Reg. Health & Welfare Fund v. Amgen, Inc.*, 400 Fed. Appx. 255, 257 (9th Cir. 2010); *Travelers Indem. Co. v. Cephalon, Inc.*, 32 F. Supp. 3d 538, 555-556 (E.D. Pa. 2014), *aff'd*, 620 Fed. Appx. 82 (3d Cir. 2015); *Emp'r Teamsters-Local Nos. 175/505 Health & Welfare Trust Fund v. Bristol Myers Squib Co.*, 969 F. Supp. 2d 463, 572-575 (S.D. W.Va. 2013); *Dist. 1199P Health & Welfare Plan v. Janssen, L.P.*, 784 F. Supp. 2d 508, 522-523 (D.N.J. 2011); *Pa. Emp. Benefit Trust Fund v. Zeneca, Inc.*, 710 F. Supp. 2d 458, 480, 485-486 (D. Del. 2010); *Se. Laborers Health and Welfare Fund v. Bayer Corp.*, 655 F. Supp. 2d 1270, 1287 (S.D. Fla. 2009); *In re Actimmune Mktg. Litig.*, 614 F. Supp. 2d 1037, 1049-1052 (N.D. Cal. 2009); *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 590 F. Supp. 2d 1282, 1289-1291 (C.D. Cal. 2008); *Ironworkers Local*

This Court should do the same.

II. The RICO marketing enterprise claim fails (Count 1).

Plaintiffs' marketing enterprise RICO allegations echo—nearly verbatim—those in other MDL complaints, including *Summit* and *West Boca*. *Compare* 1AC ¶¶839-874 *with*, *e.g.*, *Summit* 2AC ¶¶814-848 and *West Boca* Compl. ¶¶812-846. The RICO marketing enterprise claim thus fails for the same reasons as in those cases: There is no cognizable RICO injury, no actual or proximate causation, no plausible enterprise, and no actionable racketeering activity. *See Summit* MTD §II; *Summit* Reply §§II.A, IV; *West Boca* MTD §II.

A. Plaintiffs have not suffered a cognizable RICO injury.

As a threshold matter, plaintiffs cannot plead a cognizable RICO injury. As explained in *Summit*, a civil RICO plaintiff must allege an injury that is "direct"; injuries "derivative [of] or passed-on [from]" third parties are insufficient. *Trollinger v. Tyson Foods, Inc.*, 370 F.3d 602, 614 (6th Cir. 2004); *see Summit* MTD §II.A; *Summit* Reply §IV.A. Plaintiffs' alleged injuries—health-care payments for enrollees related to opioid abuse, misuse, or addiction, *see* 1AC ¶928—are entirely derivative of harms to those individual enrollees, and thus do not support civil RICO

Union No. 68 v. AstraZeneca Pharm. LP, 585 F. Supp. 2d 1339, 1344-1346 (M.D. Fla. 2008); *Williams v. Purdue Pharma Co.*, 297 F. Supp. 2d 171, 176 (D.D.C. 2003); *Ind./Ky./Ohio Reg'l Council of Carpenters Welfare Fund v. Cephalon, Inc.*, 2014 WL 2115498, at *6 (E.D. Pa. May 21, 2014); *In re Bextra and Celebrex Mktg. Sales Practices and Prod. Liab.*, 2012 WL 3154957, at *8-9 (N.D. Cal. Aug. 2, 2012); *In re Actimmune Mktg. Litig.*, 2010 WL 3463491, at *10-11 (N.D. Cal. Sept. 1, 2010); *In re Yasmin & Yaz Mktg., Sales Practices & Prods. Liab. Litig.*, 2010 WL 3119499, at *7-9 (S.D. Ill. Aug. 5, 2010); *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 2010 WL 2346624, at *7-8 (D.N.J. June 9, 2010), *aff'd*, 678 F.3d 235 (3d Cir. 2012); *Cen. Reg'l Empl. Benefit Fund v. Cephalon, Inc.*, 2010 WL 1257790, at *3-4 (D.N.J. March 29, 2010); *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, 2009 WL 2043604, at *10, 15-20, 24-25, 31 (D.N.J. July 10, 2009); *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 2009 WL 1703285, at *4-8 (C.D. Cal. June 17, 2009); *Dist. 1199P Health & Welfare Plan v. Janssen, L.P.*, 2008 WL 5413105, at *9, 11-13 (D.N.J. Dec. 23, 2008).

standing. *Trollinger*, 370 F.3d 602; *see also Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 460 (2006); *Summit* MTD §II.A.1; *Summit* Reply §IV.A.1. Nor, as set forth above, is reimbursing lawfully prescribed opioids a cognizable injury absent an allegation—missing here—that the prescriptions for plaintiffs' enrollees were medically inappropriate or harmful. Courts have routinely dismissed civil RICO claims brought by third-party payors for precisely that reason. *See supra* §I; *see also*, *e.g.*, *Ironworkers*, 634 F.3d at 1363; *Dist. 1199P Health & Welfare Plan v. Janssen, L.P.*, 784 F. Supp. 2d 508, 522-523 (D.N.J. 2011); *Se. Laborers Health and Welfare Fund v. Bayer Corp.*, 655 F. Supp. 2d 1270, 1287 (S.D. Fla. 2009); *Williams v. Purdue Pharma Co.*, 297 F. Supp. 2d 171, 176 (D.D.C. 2003).

B. Plaintiffs have not pleaded direct or proximate causation.

Plaintiffs' alleged injuries are too attenuated to establish causation. *See Summit* MTD §§II.B.1, II.B.2; *Summit* Reply §II.A; *West Boca* MTD §II. Plaintiffs' derivative injuries are too remote for plaintiffs to plead the elements of direct and proximate causation under *Holmes v. SIPC*, 502 U.S. 258 (1992). *See also Jackson v. Sedgwick Claims Mgmt. Servs., Inc.*, 731 F.3d 556, 565 (6th Cir. 2013). The causal chain here is even further attenuated because plaintiffs acknowledge that sophisticated "third-party administrators" recommend which prescription medications plaintiffs' formularies ought to include; and the formularies, in turn, determine which medicines will be reimbursed and for what amount. 1AC ¶¶682, 698; *see also* 1AC ¶¶682-710. The alleged injuries here, therefore, are even further removed from the manufacturer defendants because the proposed causal chain requires even more links: (a) Pharmacy benefit managers (like Express Scripts) recommended formulary coverage for opioid medicines solely because of manufacturer defendants' purported misrepresentations, rather than the FDA-approved labeling and their own independent knowledge and experience, *see* 1AC ¶¶687, 691; (b) third-party administrators (like

MMO) and their sophisticated committees developed formulary options that included prescription opioids based solely on these recommendations, rather than on other independent factors and considerations, *see* 1AC ¶¶684-689, 692; and (c) third-party payors (like plaintiffs) voluntarily selected formulary options that included opioid medications, and chose to reimburse their enrollees for prescription opioids—including for long-term treatment of chronic non-cancer pain—solely because of this advice, rather than cost considerations, patient needs, and other variables, *see* 1AC ¶¶682-683, 687. These additional intervening links, coupled with the independent decision-making of doctors, distributors, pharmacies, and patients, make the RICO claim here even more untenable. *See Anza*, 547 U.S. at 460; *Holmes*, 502 U.S. at 268; *Allegheny Gen. Hosp. v. Philip Morris, Inc.*, 228 F.3d 429, 443-444 (3d Cir. 2000).

C. Plaintiffs have not pleaded an enterprise.

The amended complaint does not adequately plead a marketing enterprise, including for failure to allege a "common purpose" or a "framework or superstructure." *See Boyle v. United States*, 556 U.S. 938, 948 (2009); *Ouwinga v. Benistar 419 Plan Servs., Inc.*, 694 F.3d 783, 793 (6th Cir. 2012); *see generally Summit* MTD §II.B.3; *Summit* Reply §IV.B.1; *West Boca* MTD §II.

D. Plaintiffs have not pleaded actionable racketeering activity.

Finally, plaintiffs have not pleaded any predicate act with the requisite particularity. *See Summit* MTD §II.B.4; *Summit* Reply §IV.B.2; *West Boca* MTD §II. Plaintiffs allege predicate acts of federal mail and wire fraud under 18 U.S.C. §§1341 and 1343, respectively, but as in the prior cases, plaintiffs fail to plead a single misrepresentation or omission that supposedly caused a doctor to write a medically inappropriate prescription for any patient covered under plaintiffs' health plans. Missing from the amended complaint are any of the critical factual details—the "who, what, when, and where"—of any such fraud, as required under Rule 9(b). Instead, plaintiffs broadly

allege that they were defrauded—through their third-party administrators, who in turn were defrauded by pharmacy benefit managers—and approved prescriptions that they otherwise would not have approved. *See* 1AC ¶¶693-710; *see also* 1AC ¶¶711-762.

But plaintiffs identify no specific false statements (who, what, when, where) made by any manufacturer defendant to a pharmacy benefit manager or a third-party administrator, much less allege reliance on those statements *by plaintiffs* when they chose to add opioid medications to their formularies or to reimburse enrollees for opioid prescriptions. *See Carpenters*, 2014 WL 2115498, at *6 (rejecting similar claims by third-party payors). Moreover, plaintiffs and their third-party administrators are sophisticated entities that employ "pharmacists, physicians and practicing participating providers," and they have long had access to the labeling, risks, and indications for the opioid medicines that they place on their formularies. 1AC ¶685. Given the FDA-approved labeling and risk information, plaintiffs could not have reasonably relied on any alleged fraudulent statements or omissions. Tellingly, plaintiffs fail to identify a single prescription that they otherwise would not have reimbursed but for the allegedly fraudulent conduct. This is fatal to their claims.

III. The RICO supply-chain enterprise claim fails (Count 2).

Plaintiffs' allegations of a supply-chain enterprise simply parrot those in *Summit*. *Compare* 1AC ¶¶875-903 *with Summit* 2AC ¶¶849-877. Accordingly, they fail to state a claim for relief for the reasons in *Summit* MTD §III and *Summit* Reply §§II.B, V.

A. Plaintiffs lack standing and improperly seek to circumvent the Controlled Substances Act.

Plaintiffs lack prudential standing for at least two reasons. *First*, the alleged injuries are purely derivative: the funds seek to recover the cost of covering their members' treatment for opioid and street-drug addiction and misuse, *see* 1AC ¶960, which the purported supply-chain

enterprise supposedly facilitated. As with the marketing enterprise claim, the funds' supply-chain enterprise claim is thus barred by the direct-injury requirement. *See supra* §II.A; *Summit* MTD §II.A.1; *Summit* Reply §IV.A.1. *Second*, these allegations of a supply-chain enterprise attempt to hold the manufacturer defendants liable for supposed breaches of their duties under the Controlled Substances Act (CSA), 21 U.S.C. §§801 *et seq.*, and related regulations to monitor for, and report, suspicious opioid orders, 21 CFR §§1301.71-1301.74. *See* 1AC ¶¶472, 484, 489, 552, 939-941. But the manufacturer defendants' obligations under the CSA, if any, are *to DEA*—not to the plaintiff health and welfare funds, which have no private right of action under the CSA and are thus barred from using RICO to usurp the federal government's exclusive CSA-enforcement authority. *See Summit* MTD §III.A; *Summit* Reply §V.A.

B. Plaintiffs have not pleaded direct or proximate causation.

Plaintiffs' allegation that the supply-chain defendants' purported CSA violations "directly and proximately caused" the "opioid epidemic" and the plaintiff's resulting injuries, 1AC ¶957, fails for at least two reasons. *First*, the allegations do not plausibly demonstrate direct causation. As in *Summit*, plaintiffs have not connected any manufacturer defendant's alleged CSA violations to the alleged injuries. For example, plaintiffs have not tied a CSA violation to a specific increase in the volume of opioid shipments into Ohio, or to a specific enforcement action DEA failed to take in Ohio, or to a specific national production quota DEA might have reduced (and a corresponding impact in Ohio) but for the violation. *See Summit* MTD §III.B.1; *Summit* Reply §II.B. And plaintiffs have failed to allege facts linking any of these alleged failures to a specific opioid prescription that plaintiffs actually reimbursed.

Second, the alleged connection between the manufacturer defendants' purported failures to report suspicious orders and plaintiffs' alleged injuries is too indirect, attenuated, and speculative

to establish proximate causation. *See Summit* MTD §III.B.2; *Summit* Reply II.B. Some of those links involve unlawful conduct by third parties—for instance, the failures of distributors and pharmacies to report their suspicious orders, or the deliberate criminal activity of rogue pharmacies, doctors, and even patients. *See*, *e.g.*, 1AC ¶¶877-879, 884-885, 889, 892, 896. Other links are entirely speculative—for instance, that any particular patient (much less an enrollee in one of the plaintiff funds) was harmed by the diversion of a suspicious order. *Ibid.*

C. Plaintiffs have not pleaded an enterprise.

The amended complaint does not adequately plead a supply-chain enterprise. *See Summit* MTD §III.B.3; *Summit* Reply §V.B.1. The conclusory allegation of an agreement among competitors not to report suspicious orders lacks supporting factual allegations. *See* 1AC ¶880. At best, the amended complaint rests on a suggestion that each manufacturer independently engaged in parallel, profit-seeking activity. *See* 1AC ¶¶875, 896. Those allegations do not make plausible the required "common purpose." *See Summit* MTD §III.B.3; *Summit* Reply §V.B.1. And the allegations of participation in the Healthcare Distribution Alliance, *see* 1AC ¶879, merely shows constitutionally protected petitioning and other lawful activity without identifying a "framework or superstructure" for carrying out the supposed enterprise's unlawful common purpose. *See Summit* MTD §III.B.3; *Summit* Reply §V.B.1.

D. Plaintiffs have not pleaded actionable racketeering activity.

Finally, the amended complaint does not plead any conduct by a manufacturer defendant that constitutes "racketeering activity." As in *Summit*, plaintiffs allege that the manufacturers breached their obligations under the CSA and related regulations to design and operate systems to maintain effective controls against diversion, and to identify and halt suspicious orders. *See* 1AC ¶¶9, 464, 469-478. But those allegations fail to state a violation of the CSA or its regulations, let

alone ones that may serve as predicate acts of "racketeering activity." *See Summit* MTD §III.B.4.a; *Summit* Reply §V.B.2.a. Nothing in the CSA or its regulations requires *manufacturers* to monitor or halt downstream orders, or to stop filling orders placed by registered distributors. *See* 21 CFR §1301.74(b). In any event, CSA reporting violations are not felonies and so cannot constitute predicate acts under RICO. *See* 21 U.S.C. §§842(a)(5), (c).

Plaintiffs' allegations of mail fraud, wire fraud, and DEA-reporting fraud, *see* 1AC ¶¶940, 942, do not save their claim. The allegations of such conduct are entirely conclusory, unsupported by any factual detail (much less with the particularity Rule 9(b) requires), and based on the flawed legal premise that manufacturers have a duty to monitor, report, or halt downstream orders.[4] *See* 1AC ¶¶464-569, 857-903. As a result, they fail to state a plausible claim, much less with the particularity required by Rule 9(b). *See Summit* MTD §III.B.4.b; *Summit* Reply §V.B.2.b.

IV. The state-law claims are preempted.

Federal law preempts plaintiffs' state-law claims. *See Summit* MTD §IV; *Summit* Reply §III; *see also*, *e.g.*, *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 488-489 (2013); *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 394 (6th Cir. 2013). Plaintiffs allege that the manufacturer defendants falsely represented opioids as safe and effective for the long-term treatment of chronic, non-cancer pain, *see*, *e.g.*, 1AC ¶¶10-11, 141-145, 322, 348, 367-369, 1068—even though FDA has approved most of the medications at issue here for *exactly* that purpose. And to the extent plaintiffs allege off-label promotion, federal law preempts that claim too: "The restrictions and guidelines placed upon pharmaceutical companies for off-label promotion entirely depend upon the statutory and regulatory scheme created by the FDCA," which "does not provide a private right of action" to

[4] DEA reporting fraud under 21 U.S.C. §843(a)(4) does not even qualify as a predicate act under RICO. *See Summit* MTD §III.B.4.b.

enforce its provisions. *Perdue v. Wyeth Pharm., Inc.*, 209 F. Supp. 3d 847, 851-852 (E.D.N.C. 2016).

Likewise, any claim alleging that the manufacturer defendants had a duty not to sell or ship their prescription opioids, *see* 1AC ¶¶958, 964, undermines FDA's decision to make these medications available to the public. *See Zogenix, Inc. v. Patrick*, 2014 WL 1454696, at *2 (D. Mass. Apr. 15, 2014); *see also Summit* MTD §IV; *Summit* Reply §III. Plaintiffs' state-law claims conflict with FDA's regulatory decisions regarding the approval and labeling of the manufacturer defendants' medications, FDA's exclusive enforcement authority with respect to off-label promotion, and FDA's decision to approve the manufacture and sale of these medications to the public. *See Summit* MTD §IV; *Summit* Reply §III.

V. The OCPA claims fail (Counts 3 and 4).

Plaintiffs' RICO and OCPA allegations are substantially identical to those in *Summit*. *Compare* 1AC ¶¶839-999 *with Summit* 2AC ¶¶814-973. Accordingly, plaintiffs' OCPA claims fail for the same reasons explained in *Summit* MTD §V and *Summit* Reply §VI. Here too, "the analysis of the federal RICO claim 'applies equally' to the analysis of the OCPA claim," *Aaron v. Durrani*, 2014 WL 996471, at *8 (S.D. Ohio Mar. 13, 2014), and Counts 3 and 4 should be dismissed for the failure to plead but-for or proximate causation, *see supra* §§II.B, III.B; *see also supra* §I; the existence of the marketing or supply-chain enterprises, *see supra* §§II.C, III.C; or any actionable racketeering activity, including with the particularity required under Rule 9(b), *see supra* §§II.D, III.D.

Further, as explained in *Summit* MTD §V and *Summit* Reply §VI, plaintiffs cannot state an OCPA claim because they do not allege a "pattern of corrupt activity." *See* Ohio Rev. Code §§2923.31(I), 2923.31(A)(I). Unlike the federal RICO statute, the OCPA requires a "pattern of

corrupt activity" to "include at least one *incident* other than a violation of" the federal mail, wire, or securities fraud statutes. §2923.34(A) (emphasis added). This language "refers not to the *criminal offenses asserted* but to the *factual allegations* which underlie those criminal offenses." *Rahimi v. St. Elizabeth Med. Ctr.*, 1997 WL 33426269, at *2 n.1 (S.D. Ohio July 16, 1997) (emphases in original). Plaintiffs' cursory allegations of Ohio telecommunications fraud, *see* 1AC ¶¶970, 981, 989, do not qualify as a standalone "incidents" because they are not factually separate and distinct from the alleged mail or wire fraud. In fact plaintiffs *concede* that the acts underlying the federal mail and wire fraud "*also* constitute a pattern of telecommunications fraud." 1AC ¶970 (emphasis added); *see also* 1AC ¶981. This dooms their OCPA claim. *See* Ohio Rev. Code §2923.31(E) ("incidents" must be "not so closely related to each other and connected in time and place that they constitute a single event"); *Cap City Dental Lab, LLC v. Ladd*, 2016 WL 4573993, at *10 (S.D. Ohio Sept. 1, 2016); *Rahimi*, 1997 WL 33426269, at *2 n.1. Nor do the alleged violations of 21 U.S.C. §843(a)(4)(A) qualify as "corrupt" acts under the OCPA, *see* 1AC ¶¶987, for the reasons given in *Summit* MTD §V, *Summit* Reply §VI, and *supra* §III.D.

VI. OPLA abrogates the common-law and statutory public nuisance claims (Counts 5 and 6).

For the reasons explained in *Summit* MTD §VI, which in turn incorporates *Summit* Distribs.' MTD §II.A, the Ohio Product Liability Act (OPLA), Ohio Rev. Code §§2307.71 *et seq.*, abrogates plaintiffs' common-law and statutory public nuisance claims. Even if the claims were not abrogated, they would nevertheless fail for the other, independent reasons discussed *infra* §§VII and VIII.

VII. The common-law public nuisance claim fails (Count 6).

Plaintiffs' allegations of a common-law public nuisance mirror the deficient allegations in *Summit*, *compare* 1AC ¶¶1020-1060 *with Summit* 2AC ¶¶997-1038, and thus fail for the same

reasons in *Summit* MTD §VII and *Summit* Reply §VII: (1) The economic loss rule bars the claim, which seeks to recover purely economic losses, *e.g.*, 1AC ¶¶20, 692, 1046, 1051; (2) plaintiffs fail to plead that the manufacturer defendants' conduct actually and proximately caused "an unreasonable interference with a right common to the general public," *City of Cincinnati v. Beretta*, 768 N.E.2d 1136, 1142 (Ohio 2002) (quotation marks omitted); *see also supra* §§I, II.B, III.B; and (3) the claim is preempted, *see supra* §IV.

Plaintiffs also have not pleaded the "particular harm" necessary to show standing. In Ohio, "[t]he general rule is that a private individual lacks standing to pursue a public nuisance." *Cleveland Hous. Renewal Project, Inc. v. Wells Fargo Bank, N.A.*, 934 N.E.2d 372, 380 (Ohio App. 2010). Private persons, such as plaintiffs here, can recover "only where the injury suffered is a particular harm that is of a different kind than that suffered by the public in general"—meaning a harm that is "different in kind, rather than different in degree, from that suffered by other members of the public exercising the public right." *Kramer v. Angel's Path, L.L.C.*, 882 N.E.2d 46, 52 (Ohio App. 2007) (quotation marks omitted). Plaintiffs fail to plead any nuisance harm different in kind from the public's supposed harm. *Compare*, *e.g.*, 1AC ¶¶20, 28-29, 692, 1046-1047, 1051 (plaintiffs' supposed harm) *with*, *e.g.*, 1AC ¶¶16-20, 635-651, 669-676, 1029 (public's). Quite the contrary: The alleged harm to plaintiffs is entirely derivative of the harms purportedly suffered by the public. *See supra* §§I, II.B, III.B. This is an additional and independent ground for dismissal.

VIII. The statutory public nuisance claim fails (Count 5).

Plaintiffs' statutory public nuisance claim, which invokes the same statutes as in *Summit*, *compare* 1AC ¶¶1001, 1003, 1008, 1010 *with Summit* 2AC ¶¶975, 976, 984, 986, fails for many of the same reasons discussed above and in *Summit*: (1) lack of causation, *see supra* §§I, II.B,

III.B; (2) federal preemption, *see supra* §IV; and (3) failure to plead facts establishing a predicate violation of a statute or regulation. *See Summit* MTD §VIII; *Summit* Reply §VII. As with the common-law public nuisance claim, the statutory public nuisance claim fails for the independent reason that plaintiffs fail to allege a "particular harm" that is distinct from the harms allegedly suffered by the public. *See supra* §VII; *Brown v. Scioto Cty. Bd. of Commrs.*, 622 N.E.2d 1153, 1160 (Ohio App. 1993) (requiring plaintiff to plead a "sufficiently distinct or particular harm from the public right so as to allow recovery under a statutory public nuisance theory").

IX. The negligence claim fails (Count 7).

Plaintiffs' common-law negligence claim fails for the same reasons as in *Summit*: (1) The amended complaint fails to plead any actionable conduct; (2) it fails to plead actual and proximate causation; and (3) federal law preempts the claim. *See Summit* MTD §IX; *Summit* Reply §VIII.

The claim also fails for two additional reasons. *First*, plaintiffs do not and cannot plead that the manufacturer defendants owed a duty of care *to plaintiffs*. "The existence of a duty is a question of law for a court to decide, even if resolving that question requires the court to consider the facts or evidence." *Martin v. Lambert*, 8 N.E.3d 1024, 1030 (Ohio App. 2014) (citing *Grover v. Eli Lilly & Co.*, 591 N.E.2d 696 (Ohio 1992)). "If there is no duty, then no legal liability can arise on account of negligence. Where there is no obligation of care or caution, there can be no actionable negligence." *Martin*, 8 N.E.3d at 1030 (quoting *Jeffers v. Olexo*, 539 N.E.2d 614, 616 (Ohio 1989)). Although the amended complaint refers generally to purported duties related to marketing and distributing opioid medications, *see*, *e.g.*, 1AC ¶¶1062-1065, none of these vague allegations identifies any cognizable common-law or statutory duty owed by the manufacturer defendants *to plaintiffs* (or any other health and welfare fund). Absent a duty, the manufacturer defendants cannot be found liable for negligence.

Second, to the extent plaintiffs assert a negligence *per se* claim, 1AC ¶1082-1085, that claim also fails because under Ohio law, "a negligence *per se* claim cannot succeed if the underlying statute does not allow for a private right of action." *Rogozinsky v. Danek Med., Inc.*, 1999 WL 33537323, at *2 (N.D. Ohio July 9, 1999); *see also Chambers v. St. Mary's Sch.*, 697 N.E.2d 198, 202-203 (Ohio 1998) (no negligence *per se* liability for violations of administrative rules and regulations). Plaintiffs base their negligence *per se* claim on a handful of federal and Ohio statutes and regulations, *see* 1AC ¶1082, but none provides a private right of action. This is fatal to the negligence *per se* claim. *See Summit* MTD §IX; *Summit* Reply §VIII.

X. The fraud claim fails (Count 8).

Plaintiffs' fraud claim is premised on allegations of unlawful marketing and purported failures to maintain effective controls against opioid diversion. *See* 1AC ¶¶1096-1097. Accordingly, the fraud claim fails for the same reasons as the RICO and OCPA claims, and for the reasons explained in *Summit*: (1) Plaintiffs have not adequately pleaded actual and proximate causation, *see supra* §§II.B, III.B; (2) they have not pleaded any actionable conduct with the particularity required by Rule 9(b), *see supra* §§II.D, III.D; and (3) federal law preempts this claim, *see supra* §IV. *See Summit* MTD §X; *Summit* Reply §IX.

Nor have plaintiffs demonstrated that *they* justifiably relied on any allegedly fraudulent statement, as required by Ohio law. *See*, *e.g.*, *Graham v. American Cyanamid Co.*, 350 F.3d 496, 507 (6th Cir. 2003) ("justifiable reliance upon the representation or concealment" is an essential element of fraud under Ohio law). To the contrary, plaintiffs concede that all of the manufacturer defendants' allegedly fraudulent statements or omissions were made (if at all) to physicians, pharmacists, and other entities (like pharmacy benefit managers). *See*, *e.g.*, 1AC ¶¶143-145, 161-162, 170-177, 682-770, 1096-1097. But the Supreme Court of Ohio has unequivocally held that

"a fraud claim cannot be predicated on … misrepresentations made to third parties." *Lucarell v. Nationwide Mut. Ins. Co.*, 97 N.E.3d 458, 474 (Ohio 2018); *see also Summit* MTD §X; *Summit* Reply §IX. Besides, the claim also fails because plaintiffs have not identified *any* Ohio physician who was exposed to the allegedly deceptive marketing and who then wrote a harmful or medically unnecessary opioid prescription for one of plaintiffs' enrollees as a result of that marketing.

XI. The injury through criminal acts claim fails (Count 9).

Count 9 is a nearly verbatim restatement of the allegations in *Summit*. *Compare* 1AC ¶¶1112-1129 *with Summit* 2AC ¶¶1090-1107. Accordingly, this claim fails for the same reasons: Plaintiffs do not allege a predicate criminal conviction, as required under Ohio law, and they fail to plead a substantive violation of any of the predicate statutes. *See Summit* MTD §XI; *Summit* Reply §X .

XII. The unjust enrichment claim fails (Count 10).

As in *Summit*, plaintiffs' unjust enrichment claim fails because it is derivative of the other claims. *See Summit* MTD §XII; *Summit* Reply §XI; *see also Boladian v. UMG Recordings, Inc.*, 123 Fed. Appx. 165, 169, 171 (6th Cir. 2005). It also fails on its own terms because plaintiffs have not pleaded that *they* conferred a benefit on the manufacturer defendants, as required under Ohio law. *See Johnson v. Microsoft Corp.*, 834 N.E.2d 791, 799 (Ohio 2005). Instead, plaintiffs allege in conclusory fashion that their expenditures on "healthcare services and treatment services" "helped sustain Defendants' businesses," 1AC ¶1134-1135, and that they "conferred a benefit upon Defendants by paying for Defendants' externalities: the cost of the harms caused by Defendants' improper distribution practices," 1AC ¶1136. By this language, plaintiffs presumably intend to argue that they shouldered the manufacturer defendants' generic "externalities," as in *White v. Smith & Wesson*, 97 F. Supp. 2d 816 (N.D. Ohio 2000). But *White* was decided before

the Ohio Supreme Court decided *Johnson*, and the Northern District of Ohio has repeatedly dismissed complaints—like the amended complaint here—that fail to allege a direct economic transaction between the parties. *See Young v. Carrier Corp.*, 2014 WL 6617650, at *7 (N.D. Ohio Nov. 21, 2014); *In re Whirlpool Corp. Front-Loading Washing Prods. Liab. Litig.*, 684 F. Supp. 2d 942, 951-953 (N.D. Ohio 2009); *Hoffer v. Cooper Wiring Devices, Inc.*, 2007 WL 1725317, at *5 (N.D. Ohio June 13, 2007); *Randleman v. Fid. Nat'l Title Ins. Co.*, 465 F. Supp. 2d 812, 824 (N.D. Ohio 2006). The same result should obtain here.

XIII. The civil-conspiracy claim fails (Count 11).

Plaintiffs' allegations of a civil conspiracy echo those in *Summit*. *Compare* 1AC ¶¶318-417, 500-502, 779-783, 788 *with Summit* 2AC ¶¶352-451, 532-534, 754-758, 763. Plaintiffs thus fail to state a claim for the same reasons as in *Summit*: (1) They have not pleaded the existence of a conspiratorial agreement between *any* of the 35 separate defendants; (2) they rely only on vague and conclusory allegations of an agreement to establish a "marketing network" to "increas[e] the supply of [prescription] opioids," 1AC ¶¶771, 785, 1150, 1152; and (3) they fall back on the manufacturer defendants' participation in industry-wide trade associations, which are insufficient as a matter of law to establish a conspiracy. *See Summit* MTD §XIII; *Summit* Reply §XII. At bottom, plaintiffs allege at most only parallel conduct between business competitors, and not the existence of any unlawful agreement.

XIV. All claims should be dismissed, in part, as time-barred.

A. The applicable statutes of limitations bar the claims.

Dismissal on statute-of-limitations grounds is appropriate where "one can determine from the face of the complaint that the statute of limitations has run." *Am. Premier Underwriters, Inc. v. Nat'l R.R. Passenger Corp.*, 839 F.3d 458, 464 (6th Cir. 2016). Each of plaintiffs' claims is

subject to a statute of limitations, the *longest* of which is five years. *See Summit* MTD §XIV.A & n.49 (listing applicable limitations periods for each claim); *see also Summit* Reply §XIII. Yet the claims rely on alleged acts or omissions stretching back to the mid-1990s. *See*, *e.g.*, 1AC ¶¶156, 224, 269. Under Ohio law, each "cause of action accrue[d], and [the] statute of limitations beg[an] to run, when the [alleged] wrongful act [was] committed." *Lutz v. Chesapeake Appalachia*, *L.L.C.*, 717 F.3d 459, 473 (6th Cir. 2013). Accordingly, the Court should dismiss plaintiffs' claims to the extent they rely on alleged conduct committed before April 13, 2013—five years before plaintiffs brought suit—by defendants named in the original complaint, and before June 18, 2013 by defendants first named in the amended complaint. Nor can plaintiffs rely on more recent conduct to " 'bootstrap to recover for injuries' " caused by time-barred conduct. *Meros v. Dimon*, 2017 WL 6508723, at *7 (S.D. Ohio Dec. 20, 2017) (quoting *Klehr v. A.O. Smith Corp.*, 521 U.S. 179, 190 (1997)). Under black-letter law, "discrete acts that fall within the statutory time period do not make timely acts that fall outside the time period." *Nat'l R.R. Passenger Corp. v. Morgan*, 536 U.S. 101, 112 (2002).

B. No exception to the limitations periods applies.

The amended complaint attempts to avoid the statutes of limitations by invoking four putative exceptions: the discovery rule, fraudulent concealment, equitable tolling, and the continuing violation doctrine. *See* 1AC ¶¶792-802. These generic allegations simply parrot those in *Summit* 2AC ¶¶767-777, and so fail for the same reasons. *See Summit* MTD §XIV.B; *Summit* Reply §XIII. Some of the allegations to support these exceptions involve acts by third parties, *see*, *e.g.*, 1AC ¶796, or acts that took place after the limitations periods had already expired, *see*, *e.g.*, 1AC ¶800. Neither can suspend any limitations periods as a matter of law. *See Chandler v. Wackenhut Corp.*, 465 Fed. Appx. 425, 428 (6th Cir. 2012) ("wrongful acts of a third party" do

not suspend limitations period); *Gould Elecs., Inc. v. Livingston Cty. Road Comm'n*, 2012 WL 5817937, at *12 (E.D. Mich. May 25, 2012) (acts after limitations period expired do not toll limitations period). At any rate, plaintiffs' conclusory assertions should be disregarded under *Twombly* and do not suspend or toll the applicable limitations periods for the reasons given in *Summit* MTD §XIV.B and *Summit* Reply §XIII.

CONCLUSION

All claims in the amended complaint against the manufacturer defendants should be dismissed with prejudice.

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Respectfully submitted,

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LOCAL RULE 7.1(f) CERTIFICATION

I certify that this case has been designated a "complex case" under CMO One §2(h) [Dkt. 232], and that this memorandum adheres to the page limitations for complex cases set forth in Local Rule 7.1(f).

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